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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Kalman Bolla

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EXAMINER

JACKSON, BRANDON LEE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/547,336	Applicant(s) BOLLA, KALMAN	
	Examiner BRANDON JACKSON	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-23 and 28-30 is/are rejected.
- 7) ☒ Claim(s) 24-27 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/11/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to amendments/arguments filed 10/11/2007.

Currently, claims 15-31 are pending in the instant application.

Response to Arguments

Applicant's arguments with respect to claims 15-31 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 15 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim language "including the fractured rib" and "at the least the neighboring ribs" is an attempt to claim something that is naturally occurring, in this case ribs and this is non patentable subject matter. This limitation should be cancelled from the claim or amended to recite that the device is "adapted for use with" or "attached to" the ribs.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the claims dated 10/11/2007 include the limitation of a "single-pieced" splint element. After a thorough review of the specification and the drawings, the device of the instant application does not disclose the element to be of a single piece. There is not support for such an amendment it is considered new matter and must be cancelled from the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant claims the splint element is fitted to the outside contour of the thorax without any additional aid or tool, however, Applicant's device is fitted to the user via adhesive, which could be considered an additional aid.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, because the word "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). However, for purpose of examination, Examiner will treat the limitation following preferably as though it is not essential to the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 15-19, 21-22, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rolnick et al. US 6,971,995. Rolnick et al. discloses a device (fig. 1) characterized in that the immobilizing device comprises a flat splint element (2) being rigid itself covering a large portion of the fracture area and that the side of immobilizing device facing the body is provided with an appropriate adhesive layer (col. 3, lines 66- col. 4, line 1!) for adhering the immobilizing device to the body. Rolnick et al. does not expressly state that the splint element is of a single piece, however the applicant has not provided any criticality to this claimed feature. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to have the splint element be single-pieced or of multiple pieces because the applicant has not

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disclosed that the single-pieced element is used for a particular purpose, provides an advantage, or solves a stated problem. Where the instant specification and evident of record fail to attribute any significant (novel or unexpected results) to a particular arrangement, the particular arrangement is deemed to have been a design consideration within the skill of the art. In re Kuhle, F.2d 553, 555, 188 USPQ 7, 9 (CCPA 1975)

As to claim 16, Rolnick et al. disclose that the splint can be fitted to the outside contour of the thorax without any addition aid or tool (via the adhesive col. 3, lines 66 - col. 4, line 1).

As to claims 17-19, Rolnick et al. substantially disclose the device as claimed, see rejection to claim 15 above, Rolnick et al. further disclose that the splint members are elastomeric, therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to use a plastically deformable device for the purpose of making it conformable to the body and increasing pain comfort (col. 5, lines 1-14). As to the plastically deformable material being a plastic or metal plate it would have been obvious to one having ordinary skill in the art to use either material because it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Therefore, it would have been an obvious matter of design choice to use plastic or metal in the device of Rolnick et al. for making the most comfortable splint device.

As to claim 21, Rolnick et al. disclose that the splint element may be provided with a covering (col. 4, lines 12-14).

As to claim 22 and 28, Rolnick et al. disclose that the splint element may contain foam (col. 3, lines 64-66).

Claims 20, 23, and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rolnick et al. as applied to claim 15 above, and further in view of Bolla et al. US 6,039,706. Rolnick et al. substantially disclose the invention as claimed; see rejection to claims 15, 18, and 19 above; but does not expressly state that the plastically deformable metal plate is corrugated. Bolla et al. teaches the use of sheet metal (2) being corrugated (42) in a splint device. Bolla et al. further discloses that the sheet metal is easily shaped yet permits immobilization (col. 1, lines 20-25). Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to use the plastically deformable metal with corrugations as taught by Bolla et al. in the device of Rolnick et al. for the purpose allowing the splint to adapt to local irregularities in the extremities or body parts (col. 2, lines 5-13).

As to claim 23, the above combination teaches the use of a foil (aluminum/metal sheet) in the splint device. The limitations that it is used for protecting covering of the upper side of the splint element is an intended use limitation.

Claims 29 & 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rolnick et al. in view of Bolla et al. US 6,039,706.

As to claim 29, Rolnick et al. disclose a device (fig. 1) characterized in that the immobilizing device comprises a flat splint element (2) being rigid itself covering a large portion of the fracture area and that the side of immobilizing device facing the body is provided with an appropriate adhesive layer (col. 3, lines 66- col. 4, line 1!) for adhering the immobilizing device to the body. Rolnick et al. does not expressly state that the splint element is of a single piece, however the applicant has not provided any criticality to this claimed feature. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to have the splint element be single-pieced or of multiple pieces because the applicant has not disclosed that the single-pieced element is used for a particular purpose, provides an advantage, or solves a stated problem. Where the instant specification and evident of record fail to attribute any significant (novel or unexpected results) to a particular arrangement, the particular arrangement is deemed to have been a design consideration within the skill of the art. In re Kuhle, F.2d 553, 555, 188 USPQ 7, 9 (CCPA 1975).

Rolnick et al. substantially disclose the invention as claimed, but does not expressly state that the plastically deformable metal plate is corrugated. Bolla et al. teaches the use of sheet metal (2) being corrugated (42) in a splint device. Bolla et al. further discloses that the sheet metal is easily shaped yet permits immobilization (col. 1, lines 20-25). Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to use the plastically deformable metal with corrugations as taught by Bolla et al. in the device of Rolnick et al. for the purpose allowing the splint to adapt to local irregularities in the extremities or body parts (col. 2, lines 5-13).

As to claim 30, Rolnick et al. disclose a device (fig. 1) characterized in that the immobilizing device comprises a flat splint element (2) being rigid itself covering a large portion of the fracture area and that the side of immobilizing device facing the body is provided with an appropriate adhesive layer (col. 3, lines 66- col. 4, line 1) for adhering the immobilizing device to the body. Rolnick et al. substantially disclose the invention as claimed, but does not expressly state that the adhesive layer is provided with the analgesic agent but it would have been obvious to one having ordinary skill in the art at the time of the invention to have the agent be on the adhesive layer so that it can contact the patient and increase pain relief (col. 5, lines 21-25). Rolnick et al. does not expressly state the use of a protective foil.

Bolla et al. teaches the use of a foil (aluminum/metal sheet) in the splint device and further disclose that the sheet metal is easily shaped yet permits immobilization (col. 1, lines 20-25). Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to use the plastically deformable metal with corrugations as taught by Bolla et al. in the device of Rolnick et al. for the purpose allowing the splint to adapt to local irregularities in the extremities or body parts (col. 2, lines 5-13).

Allowable Subject Matter

Claim 24-27 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **BRANDON JACKSON** whose telephone number is (571)272-3414. The examiner can normally be reached on Monday - Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brandon Jackson/
Examiner, Art Unit 3772

BLJ

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772